UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHERN DIVISION

ANGELA ABT,	)	
	)	
Plaintiff(s),	)	
	)	
vs.	)	Case No. 1:20-cv-0047 SRC
	)	
ETHICON, INC., et al.,	)	
	)	
Defendant(s).	)	

MEMORANDUM AND ORDER

In 2014, Plaintiff Angela Abt had a medical device implanted in her to relieve certain medical conditions. After implantation of the device, she encountered several complications and filed suit against Defendants Ethicon Inc. and Johnson and Johnson seeking relief for her injuries. The Defendants move for summary judgment [55], claiming that Abt's experts simply do not support her case.

I. BACKGROUND

The specific device Abt had implanted was Defendants' TVT-O device. The TVT-O device is a mid-urethral sling used to manage a bladder condition known as stress urinary incontinence. An MDL was created in the United States District Court for the Southern District of West Virginia to handle pretrial matters for all cases involving "mesh products" like the product at issue here. Abt filed a short-form complaint in the MDL in April 2015 asserting 17 counts. In March 2020, the MDL transferred Abt's case to this Court for trial. All that remains for this Court to decide is a case-specific summary judgment motion and several case-specific *Daubert* motions. After transfer to this Court, Abt dismissed most of the counts asserted in her short-form complaint. Her remaining causes of action are negligence, strict liability – failure to

warn, and strict liability – design defect. Defendants now move for summary judgment on Abt's remaining claims. The Court grants the motion and dismisses the remainder of Abt's claims.

II. UNCONTROVERTED FACTS

In 2014, Abt suffered from stress urinary incontinence and had surgery with Dr. Luis Mertins to implant the TVT-O. The procedure took place at Mercy Hospital Jefferson in Festus, Missouri. Abt has been a Missouri resident since at least 2000, and her relevant medical care and treatment, including a subsequent mesh excision surgery, occurred in Missouri.

Abt's implanting physician, Dr. Mertins, testified additional warnings by Ethicon would not have changed his decision to prescribe TVT-O for Abt. He testified he stands by his prescribing decision.

Abt has designated one case-specific expert, Dr. John P. Brennan. In his report, Dr. Brennan concluded the defective mesh implanted in Abt caused her symptoms and complications. However, he did not identify any specific defect in the TVT-O's design or opine that any specific defect caused Abt's injuries.

III. STANDARD

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment shall be entered "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In ruling on a motion for summary judgment, the Court is required to view the evidence in the light most favorable to the non-moving party and must give that party the benefit of all reasonable inferences to be drawn from the underlying facts. *AgriStor Leasing v. Farrow*, 826 F.2d 732, 734 (8th Cir. 1987). The moving party bears the initial burden of showing both the absence of a genuine issue of material

fact and entitlement to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); Fed. R. Civ. P. 56(c).

In response to the proponent's showing, the opponent's burden is to "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Fed. R. Civ. P. 56(e)). Self-serving, conclusory statements without support are insufficient to defeat summary judgment. *Armour and Co., Inc. v. Inver Grove Heights*, 2 F.3d 276, 279 (8th Cir. 1993). Rule 56(c) "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

III. DISCUSSION

Defendants argue that all of Abt's remaining claims fail for lack of causation.

A. Failure to Warn Claim

In Missouri,[1] the elements of a cause of action for strict liability failure to warn are: "(1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011). Causation in a failure to warn case requires that the product with the missing warning cause the plaintiff's injuries and that a warning would have

[1] The parties agree that the Court should apply Missouri law.

altered the behavior of the user of the product. *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992). A rebuttable presumption applies that "a warning, if provided, will be read and heeded." *Johnson v. Medtronic, Inc.*, 365 S.W.3d 226, 232 (Mo. Ct. App. 2012); *Grady v. Am. Optical Corp.*, 702 S.W.2d 911, 918 (Mo. Ct. App. 1985).

Missouri courts apply the learned intermediary doctrine in prescription drug and medical equipment or device cases involving failure to warn claims. *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999); *Kirsch v. Picker Intern., Inc.*, 753 F.2d 670, 671 (8th Cir. 1985) (applying Missouri law). Under this doctrine, "a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." *Doe*, 3 S.W.3d at 419. "[A]ny warning given to the physician is deemed a warning to the patient." *Id*.

Defendants assert that Abt's implanting physician, Dr. Mertins, testified he would not have changed his diagnosis even if provided additional warnings by Ethicon. Therefore, according to Defendants, Abt cannot show the implant caused her injuries because she cannot show additional warnings would have altered the behavior of her physician. The Court agrees.

Abt provides no evidence that Defendants' alleged failure to warn caused her injuries. While a rebuttable presumption arises that a person will heed a warning if one is provided, Defendants have rebutted that presumption with Dr. Mertins's testimony. He testified he stands by his decision to select the TVT-O for Abt, that he would not have changed his decision to implant the TVT-O in Abt even if the instructions for its use had included each of the additional risks Abt alleges were not included, and that he relied more on medical literature (rather than manufacturer's warnings) in deciding what implants to use. Doc. 57, pgs. 29, 34, 47-48; transcript pgs. 41:6-8, 61:8-11, 111:21-115:1, 116:17-21. With Dr. Mertins's testimony, Abt

cannot connect her injuries to Defendants' alleged failure to warn, because additional warnings would have had no effect on Dr. Mertins.

Other courts have found similarly when applying the learned intermediary doctrine in cases alleging claims of strict liability for failure to warn. *See Contreras v. Boston Sci. Corp.*, No. 2:12-cv-03745, 2016 WL 1436682 at *4 (S.D. W. Va. Apr. 11, 2016) (finding plaintiffs cannot establish proximate causation where there is no evidence the implanting physician would have taken a different course of action even if provided an adequate warning); *Hull v. Ethicon, Inc.*, No. 3:20-cv-00038 JMS-DML, 2020 WL 1154577 at *9 (S.D. Ind. Mar. 10, 2020) (same); *Cutter v. Ethicon, Inc.*, No 5:19-443-DCR, 2020 WL 109809 at *9 (E.D. Ky. Jan. 9, 2020) (same).

Abt points to her own testimony, arguing she would have changed her decision if she had been warned of all of the risks. Under the learned intermediary doctrine though, Defendants' duty to warn is to the physician, not to the patient. *See Doe*, 3 S.W.3d at 419. Therefore, Abt's testimony alone cannot create the requisite causal link between her injuries and Defendants' failure to warn. Abt failed to produce any evidence that Defendants' alleged failure to adequately warn Dr. Mertins of the risks of the implant caused Abt's injuries. Thus, the Court grants summary judgment to Defendants and dismisses this claim.

B. Design Defect Claim

Defendants also argue Abt lacks evidence that a design defect in the TVT-O caused her injuries. In Missouri, the plaintiff bears the burden to demonstrate that the product design was defective and that the defect caused the plaintiff's injury. *Pritchett v. Cottrell, Inc.*, 512 F.3d 1057, 1063 (8th Cir. 2008) (citing *Richcreek v. Gen. Motors Corp.*, 908 S.W.2d 772, 776 (Mo. Ct. App. 1995)). "The 'heart and soul' of a strict liability design defect case is unreasonable

danger and causation." *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008) (quoting *Nesselrode v. Exec. Beechcraft, Inc.*, 707 S.W.2d 371, 376 (Mo. 1986)). "A plaintiff proves causation in a product defect case 'by providing competent expert testimony or additional evidence that the defendant's product was a substantial factor in causing the injury.'" *Mathes v. Sher Express, LLC*, 200 S.W.3d 97, 103 (Mo. Ct. App. 2006) (quoting *Dorman v. Bridgestone/Firestone, Inc.*, 992 S.W.2d 231, 237 (Mo. Ct. App. 1999)).

In support of her design defect claim, Abt relies on two experts, Dr. Bruce Rosenzweig and Dr. John Brennan. In his report, Dr. Rosenzweig discusses the various design defects he found in the TVT-O. Dr. Brennan's expert report focused on Abt and her injuries. After summarizing Abt's medical history concerning the TVT-O and listing her complications, Dr. Brennan concluded:

> In reviewing Angela Abt's medical records, I have considered her pre-implant medical and surgical history, and utilized my education, experience, and training in performing a differential diagnosis to rule out any other potential causes of Angela Abt's pelvic injuries. To a reasonable degree of medical certainty, the defective mesh implanted in Angela Abt in September 2014 was the cause of her multiple symptoms and complications.

Doc. 62-4. No where in Dr. Brennan's report does he connect a design defect with Abt's injuries. He conclusorily states that generally the defective device caused Abt's injuries. He provided no specifics such as what design defect caused what injuries, or how any design defect caused Abt's injuries. He essentially concludes that the mere presence of the TVT-O caused Abt's injuries.

Dr. Brennan could have relied on Dr. Rosenzweig's report about the design defects to make a connection to Abt's injuries. *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d 1004, 1033 (E.D. Mo. 2009) ("It is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the

first expert."). However, he did not, instead relying solely on his general conclusion that the defective product caused Abt's injuries; he therefore failed to tie an alleged design defect to the injury, which Missouri law requires. *Richcreek*, 908 S.W.2d at 776 (To establish liability, a plaintiff must show the product is defective, as designed, and that the "demonstrated defect caused his injuries."); *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008) (same); *see also Lewis v. Johnson & Johnson*, 601 Fed. App'x 205, 211 (4th Cir. 2015) (affirming directed verdict for defendants where expert testified the presence of the TVT caused plaintiff's pain but did not testify that a defect in the TVT caused her pain); *Lampron v. Johnson & Johnson*, No. 20-CV-317-JD, 2020 WL 3452150 at * (D. N.H. June 24, 2020) (granting summary judgment to defendants where expert did not identify a design defect in the mesh product that caused plaintiff's complications).

Considering Dr. Rosenzweig's report with Dr. Brennan's report, at most Abt has established correlation between the implant's design defects and her injuries; she has not shown causation. Without some evidence showing her implant caused her injuries, beyond conclusory statements, Abt's claim for strict liability design defect fails. As such, the Court grants summary judgment to Defendants and dismisses this claim.

C. Negligence Claim

For the same reasons that her design defect claim fails, Defendants argue her negligence claim also fails – lack of causation. Abt argues that Missouri law treats strict liability and negligence claims differently and therefore, they do not involve the same causation analysis.

In Missouri, the courts do treat strict liability and negligence claims differently. The distinction is that in a negligence claim the "duty is based upon the foreseeability of harm or injury from defendant's conduct" while in a strict liability claim, "the liability arises because of

the foreseeable use of the product, not the foreseeable harm." *Racer v. Utterman*, 629 S.W.2d 387, 395 (Mo. Ct. App. 1981) (citing *Blevins v. Cushman Motors*, 551 S.W.2d 602 (Mo. banc 1977)). However, whether under a theory of negligence or strict liability, "one essential element that the plaintiff must prove in a products liability case is that the defect in the product or the negligence of the manufacturer was the proximate cause of the injuries sustained by the plaintiff[.]" *Willard v. Bic Corp.*, 788 F. Supp. 1059, 1063 (W.D. Mo. 1991) (citing *Garrett v. Jos. Schlitz Brewing Co.*, 631 S.W.2d 652, 654 (Mo. Ct. App. 1982)).

For the same reasons Abt's failure to warn and design defect claims failed, her negligence claim must also fail. Abt produces no evidence to establish Defendants' actions caused her injuries. In her response to Defendants' motion for summary judgment, Abt argues the causation analysis is different but provides no analysis as to how it is different nor any facts to support her argument or establish causation. Thus, the Court grants summary judgment to Defendants and dismisses this claim.

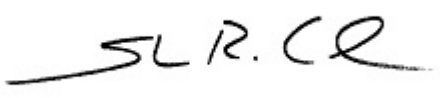
Accordingly,

IT IS HEREBY ORDERED that Defendants' Amended Motion for Summary Judgment [55] is **GRANTED**. The Court dismisses all claims with prejudice.

IT IS FURTHER ORDERED that Defendants' Motion for Partial Summary Judgment [16] is **DENIED**, as moot due to the filing of the Amended Motion.

IT IS FURTHER ORDERED that Defendants' Motion to Resolve Outstanding Daubert Issues [63] is **DENIED**, as moot.

So Ordered this 20th day of August, 2020.



STEPHEN R. CLARK
UNITED STATES DISTRICT JUDGE